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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,215	03/27/2001	Scott A. Waldman	08321-0166 US	2195

35148 7590 07/28/2005

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EXAMINER

CALAMITA, HEATHER

ART UNIT PAPER NUMBER

1637

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No.	Applicant(s)	
	09/820,215	WALDMAN ET AL.	
	Examiner	Art Unit	
	Heather G. Calamita, Ph.D.	1637	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 15 July 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: The claims would have to be searched again for the limitation "to reduce false positives". (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: \_\_\_\_\_.


Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see continuation sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_
13. ☐ Other: \_\_\_\_\_.

  
**JEFFREY FREDMAN**  
**PRIMARY EXAMINER**  
7/27/05

11. With respect to the New Matter rejections of claims 4 and 40, applicant's arguments filed July 15, 2005, have been fully considered and are persuasive. Therefore the New Matter rejections of claims 4 and 40 have been withdrawn. With respect to the written description rejections of claims 1-4, 6-11, 13-15 and 37-47, Applicants' argument is similar to that filed on December 6, 2004 and as such the rejections are maintained for reasons already of record (Office Action mailed January 24, 2005). With respect to the 102 (b) rejections of 1, 3-4, 7-11 and 13, as discussed in the Office Action mailed January 24, 2004, Zippelius et al. teach the removal of mononuclear cells from the sample, and CD34+ cells inherently comprise mononuclear cells. Applicant appears to further argue the removal of mononuclear cells does not meet the claim limitation, however Zippelius et al. does meet the method steps as claimed. Zippelius et al. teach MNC were isolated by density gradient centrifugation, this meets the claim language of "eliminating CD34+ cells", since mononuclear cells will contain CD34+ cells. Finally with respect to the 103 rejections of claims 1, 3-4, 7-11, 13, 37-40 and 42-45, Applicants' argue no motivation to combine, Palsson et al teach away from eliminating CD34+ cells and the combination would not lead to the claimed invention. However, Ts'o et al. teach removal of mononuclear cells and Palsson is relied on to exemplify CD34+ cells in particular. Ts'o et al. by state the advantage of removing nucleated white blood cells (i.e. mononuclear cells) because the presence of these cells can interfere with cell identification, particularly for methods such as PCR, and further provides numerous examples of specific mononuclear cell types (see col. 11 lines 58-61, 67 and col. 12 lines 1-5). Palsson et al. exemplify a known specific type of mononuclear cell CD34+ and describe a method using antibodies specific to CD34+ as a means to specifically capture and remove these cells from samples, as suggested by Ts'o. Applicants further argue the references do not motivate one of skill in the art to remove CD34+ cells to remove the high false positive rate that was associated with detection methods prior to the invention. However, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). With respect to the 103 rejection of claims 6, 14, 15, 41, 46 and 47, applicant argues the examiner's conclusion of obviousness is based upon the improper application of the combination of the teachings of Ts'o et al. and Palsson et al. Applicants' arguments with respect to these rejections have been considered but are moot in view of the clarification of the application of the combination of the teachings of Ts'o and Palsson.